IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

ELIZABETH HEILMAN, individually and on behalf of all others similarly situated, Plaintiff, v. KONINKLIJKE PHILIPS N.V., PHILIPS NORTH AMERICA LLC, and PHILIPS RS NORTH AMERICA LLC, Defendants.	)	Civil Action No. CLASS ACTION

COMPLAINT

Plaintiff Elizabeth Heilman, individually and on behalf of all others similarly situated, by and through her attorneys, alleges as follows:

I. NATURE OF THE ACTION AND INTRODUCTION

1. This is a class action lawsuit brought against Defendants Koninklijke Philips N.V., Philips North America LLC, and Philips RS North America LLC (collectively "Philips" or "Defendants") by Plaintiff on behalf of herself and all other similarly situated consumers who purchased certain CPAP/BiPAP machines or ventilators manufactured and sold by Defendants.

2. Philips manufactures and sells medical equipment products. These products include Continuous Positive Airway Pressure ("CPAP") and Bilevel Positive Airway Pressure ("BiPAP") machines, which are used in the treatment of sleep apnea, and ventilators, which treat respiratory failure.

3. On June 14, 2021, Philips announced a recall of many of its CPAP/BiPAP machines and its ventilators because they suffer from a defect which could result in serious injury, permanent impairment, and even be life-threatening.

4. These products contain polyester-based polyurethane ("PE-PUR") foam which is used to minimize the sound produced by the devices. According to Philips, this PE-PUR foam can deteriorate over time, causing it to break down. When the foam breaks down, small foam particles and gases can be inhaled or ingested though use of the devices which assist patients with respiration. The foam may emit volatile organic compounds, which when inhaled, can result in serious adverse health effects, including cancer.

5. Unfortunately for patients, Philips has known about these dangers for years but did nothing to warn patients or doctors until recently.

6. Furthermore, despite the recall, Philips is still not actually repairing or replacing affected devices, which many patients rely upon on a daily basis to treat serious medical conditions. Since Philips is now telling patients it is not safe to use these devices, but many patients rely on them to treat serious health conditions, Philips leaves many patients with no safe option but to pay full price for a newer version.

7. Plaintiff purchased a Philips device included in the recall. Plaintiff would not have purchased the device or would have paid less for it if she had known about the foam problems and potential health hazards.

8. As a result of Philips's unfair, deceptive, and/or fraudulent business practices, owners of these devices, including Plaintiff, have suffered an ascertainable loss, injury in fact, and otherwise have been harmed by Philips's conduct.

II. THE PARTIES

A. PLAINTIFF

9. Plaintiff Elizabeth Heilman is a citizen and resident of Virginia.

10. Plaintiff purchased a Respironics DreamStation CPAP machine approximately three years ago through Comprehensive Sleep Care Center in Northern Virginia.

11. Prior to learning about the recall, Plaintiff used her CPAP machine every night at the advice of her doctor.

12. Upon learning of the recall, Plaintiff contacted Philips and confirmed her CPAP machine was included in the recall.

13. Plaintiff consulted with her doctors and has ordered a new machine, which she will have to pay for out of her health insurance deductible.

14. Plaintiff would not have purchased the DreamStation machine if she had known it was defective. Plaintiff seeks a refund, reimbursement for the replacement, and all other appropriate damages for all the injuries she has suffered as a result of her defective DreamStation.

B. DEFENDANTS

15. Koninklijke Philips N.V. is a Dutch multinational company headquartered in Amsterdam, Netherlands, and is the parent company of Philips North America LLC and Philips RS North America LLC.

16. Defendant Philips North America LLC is a Delaware company with its principal place of business in Cambridge, Massachusetts.

17. Defendant Philips RS North America LLC (formerly Respironics, Inc.) is a Delaware company with its headquarters and principal place of business in Murrysville, Pennsylvania.

18. At all relevant times, each Defendant acted in all aspects as the agent and alter ego of each other, and reference to "Philips" or "Defendants" herein refers to each and every Defendant individually and collectively.

III. JURISDICTION AND VENUE

19. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 of the Class Action Fairness Act of 2005 because: (i) there are 100 or more class members, (ii) there is an aggregate amount in controversy exceeding $5,000,000, exclusive of interest and costs, and (iii) there is minimal diversity because at least one plaintiff and one defendant are citizens of different states. This Court also has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.

20. Venue is proper because Philips RS North America LLC (formerly Respironics, Inc.) is headquartered in and regularly conducts business in this District and because a substantial part of the events or omissions giving rise to the claim occurred in this District.

IV. FACTUAL ALLEGATIONS

A. CPAP AND BIPAP MACHINES AND VENTILATORS

21. CPAP and BiPAP machines and ventilators are all used to treat serious respiratory conditions by helping patients to breathe.

22. CPAP and BiPAP machines are used primarily as treatment for sleep apnea.

23. Sleep apnea (sometimes called obstructive sleep apnea) is a disorder in which breathing is disturbed temporarily during sleep. Breathing may stop or become very shallow. These periods are called "apneas," and they may be associated with fatigue, daytime sleepiness, depression, interrupted sleep, or snoring, among other symptoms. Serious cases can lead to

hypertension, heart attack, or stroke, among other medical ailments. It is estimated that over 25 million Americans suffer from sleep apnea.[1]

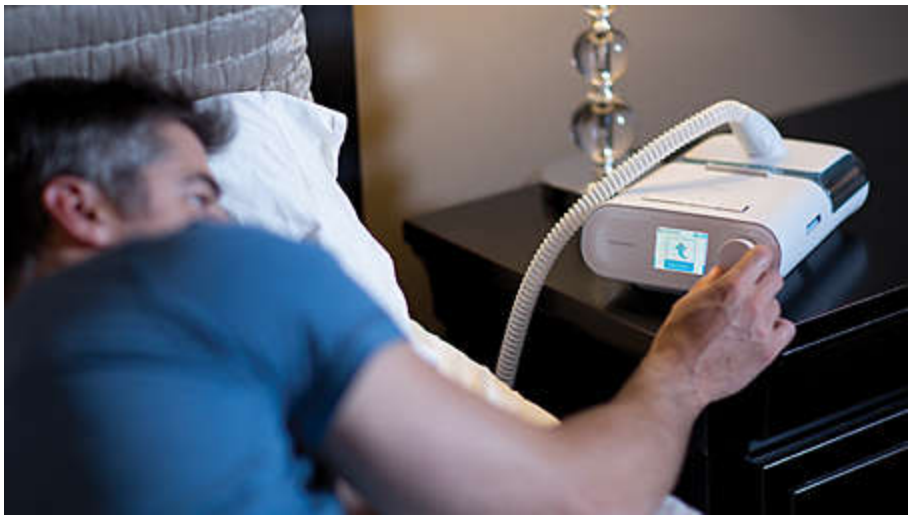
24. CPAP therapy is the most common treatment for sleep apnea. In CPAP therapy, a machine delivers a flow of air through a mask over the nose or mouth, which increases air pressure in the throat so that the airway does not collapse during inhalation. CPAP therapy assists breathing during sleep and can successfully treat sleep apnea. According to the Mayo Clinic, "CPAP is the most consistently successful and most commonly used method of treating obstructive sleep apnea."

25. BiPAP machines and Automatic Positive Airway Pressure (APAP) machines are similar devices that also treat sleep apnea. BiPAP machines use two different pressures, one for inhaling and one for exhaling. APAP machines adjust pressure automatically during the night as needed.

26. CPAP, BiPAP and APAP machines all consist of a main unit which connects to a facemask via an air hose. A patient will typically place the main unit on a nightstand and then wear the mask in bed while sleeping.

27. The following images show the general components and typical use of these machines:

[1] *See* The American Academy of Sleep Medicine, *Rising prevalence of sleep apnea in U.S. threatens public health*, available at https://aasm.org/rising-prevalence-of-sleep-apnea-in-u-s-threatens-public-health/ (last visited July 3, 2021).



28. Sleep apnea patients typically use these machines every night when they sleep. Symptoms may return quickly without continued use.

29. Unlike CPAP and BiPAP machines, ventilators (sometimes called mechanical ventilators or breathing machines) are used to treat respiratory failure.

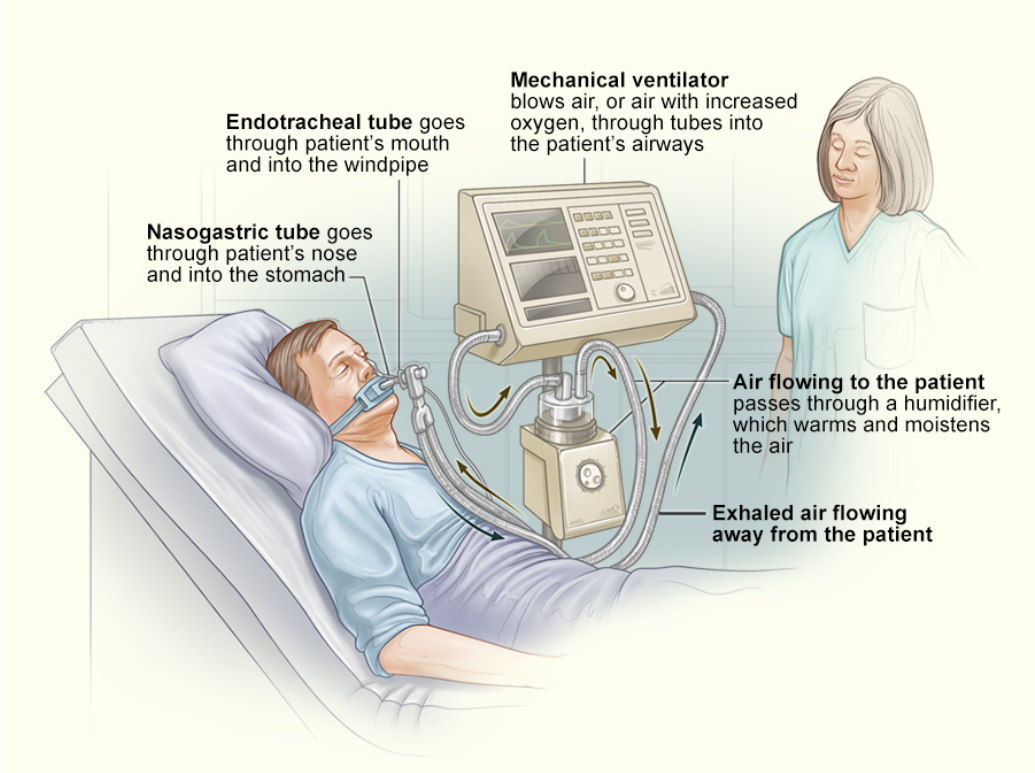
30. Respiratory failure is a condition in which a patient has difficulty breathing or getting enough oxygen into his or her blood. Many underlying conditions can cause respiratory

failure, including physical trauma, sepsis, pneumonia, COVID-19, and drug overdose. Respiratory failure can be fatal.

31. Ventilators can also be used in other circumstances, such as during surgery when general anesthesia may interrupt normal breathing. The COVID-19 crisis has led to a significant increase in the demand for ventilators.

32. A ventilator mechanically helps pump oxygen into a patient's body. The air flows through a tube that goes in the patient's mouth and down his or her windpipe.

33. The following image from the National Institute of Health shows a typical ventilator and how it works:



B. PHILIPS PRODUCTS

34. CPAP and BiPAP machines and ventilators are big business. The global sleep apnea devices market size was valued at $3.7 billion in 2020 and is expected to expand considerably in the coming years.[2] The global ventilator market size was valued at $2.99 billion in 2019[3], which was before the COVID-19 pandemic created skyrocketing demand and global shortages.

35. Philips is a major manufacturer of CPAP machines, BiPAP machines, and ventilators. Philips has sold millions of CPAP and BiPAP machines and ventilators in the United States.

36. Philips's primary line of CPAP/BiPAP machine products is the DreamStation line. The original DreamStation launched in October 2015. Philips subsequently launched a more compact version which it advertises as ideal for travel called the DreamStation Go.

37. The DreamStation products are among the bestselling sleep apnea devices on the market.

38. Philips sells DreamStation products through its Western Pennsylvania based subsidiary, Respironics (now Philips RS North America LLC), which Philips acquired in 2008.

39. Many of Philips's CPAP and BiPAP machines and ventilators contain PE-PUR foam in order to reduce sound made by the machine. As designed, air passes through this foam before it is pumped into the patient's airway. Some of the sound generated by the machine is then absorbed by the foam.

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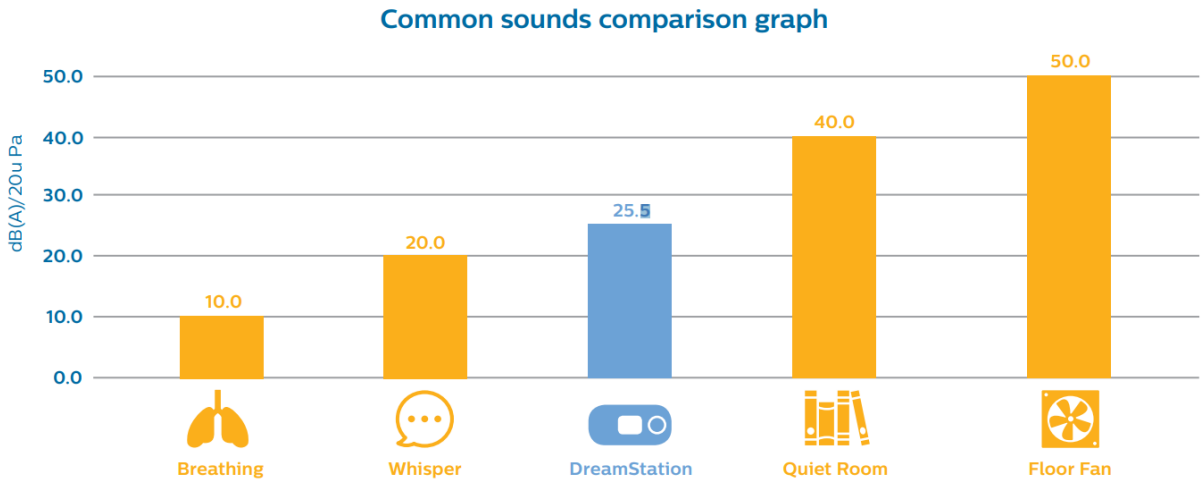
[2] *See* https://www.grandviewresearch.com/industry-analysis/sleep-apnea-devices-market (last visited July 3, 2021).
[3] *See* https://www.alliedmarketresearch.com/mechanical-ventilators-market (last visited July 3, 2021).

40. Sound reduction can be an attractive feature since patients operate these devices while they (and their partners) are sleeping. In fact, the relative quiet of DreamStation products factors prominently into Philips's marketing.[4] Philips put out information that it extensively studied and measured the amount of sound produced by DreamStation products. For example, Philips put out the following infographic indicating DreamStation products are barely louder than a whisper:



41. On April 13, 2021, Philips announced that it was launching a next-generation model of the DreamStation, called the DreamStation 2.

C. RECALL AND SERIOUS HEALTH RISKS

42. On April 26, 2021, less than two weeks after it announced the launch of the second-generation, Philips announced the recall of first-generation DreamStation products due to concerns about serious health risks.

> Philips has determined from user reports and testing that there are possible risks to users related to the sound abatement foam used in certain of Philips' sleep and respiratory care devices currently in use. The risks include that the foam may

[4] *See* https://www.documents.philips.com/assets/20170523/62e4f43a1349489ba3cca77c0169c6ef.pdf (last visited July 3, 2021).

> degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone*), and certain environmental conditions involving high humidity and temperature. The majority of the affected devices are in the first-generation DreamStation product family.

43. On June 14, 2021, Philips issued a further statement about the possible health risks stemming from deterioration of the PE-PUR foam:

> To date, Philips has produced millions of Bi-Level PAP, CPAP and mechanical ventilator devices using the PE-PUR sound abatement foam. Despite a low complaint rate (0.03% in 2020), Philips determined based on testing that there are possible risks to users related to this type of foam. The risks include that the PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone,** and high heat and high humidity environments may also contribute to foam degradation.

44. Philips further explained that it "has received reports of possible patient impact due to foam degradation. The potential risks of particulate exposure include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects. The potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and carcinogenic effects."

45. On the same day, Philips also issued "Clinical information for physicians," which explained that the foam breakdown "may lead to patient harm and impact clinical care." Philips warned doctors that the following symptoms and health effects can result:

> While there have been limited reports of headache, upper airway irritation, cough, chest pressure and sinus infection that may have been associated with the foam, based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment.

46. Deterioration of the foam can release harmful chemicals into the air that the machines are pumping into patients' lungs, including toluene diamine, toluene diisocyanate, and diethylene glycol.

47. The National Institute for Occupational Safety and Health categorizes toluene diisocyanate as "potential carcinogen." The European Union considers toluene diisocyanate "highly toxic" and has concluded that toluene diamine "cannot be considered safe for use."

48. Philips disclosed that it "has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)." The PE-PUR foam is black, and when it breaks down, it can release these particles into the airpath.

49. Harmful gasses can also be released as the foam degrades, including dimethyl diazine and Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)-.

50. Philips admitted that these harmful substances can cause: "irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve" and may lead to the following symptoms: "headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/ vomiting, toxic and carcinogenic effects," as well as "adverse effects to other organs such as kidney and liver."

51. Philips advised patients to stop using affected CPAP and BiPAP machines immediately because of the potential health risks.

52. The statement also acknowledged that it may be too dangerous for patients using affected ventilators to stop using them and more or less advised doctors to decide whether it was more dangerous to take the patient off the ventilator or to leave the patient on the defective ventilator.

53. The products affected by the recall include ("Recalled Products"):

- E30
- DreamStation ASV
- DreamStation ST, AVAPS
- SystemOne ASV4
- C Series ASV, S/T, AVAPs
- OmniLab Advanced Plus
- SystemOne (Q Series)
- DreamStation CPAP, Auto CPAP, BiPAP
- DreamStation Go CPAP, APAP
- Dorma 400, 500 CPAP
- REMStar SE Auto CPAP
- Trilogy 100 and 200
- Garbin Plus, Aeris, LifeVent
- A-Series BiPAP Hybrid A30
- A-Series BiPAP V30 Auto
- A-Series BiPAP A40
- A-Series BiPAP A30

54. Philips acknowledged that most of the devices it was recalling are still within the "advised 5-year service life" of the products.

55. Philips has admitted that the recalled products are defective and unsafe and that patients should stop using them immediately. Although still within what was supposed to be their useful life, these products are now effectively useless.

56. Had Plaintiff and Class Members known about the defect and health risks, they either would not have bought these products or would have paid significantly less for them. Plaintiff and Class Members have all suffered economic injuries as a result of their purchase of Philips CPAP and BiPAP machines and ventilators.

D. PHILIPS KNEW ABOUT THE DEFECT LONG BEFORE ISSUING THE RECALL

57. Although Philips did not disclose these health risks to its consumers or the general public until 2021, Philips knew about these health risks much earlier.

58. As noted above, when Philips announced the recall, it acknowledged it had already received complaints about black particles in the airways of the machines. The DreamStation line first launched in 2015, and several of the affected models have been on the market even longer.

59. Online message boards, review sites, and social media contain many complaints regarding black particles and foam degradation problems. Philips, like most companies, likely monitors these online forums and would have learned about the problem years ago.

60. For example, Nick Dunn, who runs the YouTube channel "CPAP Reviews," reported as soon as the recall was announced that he had known about the foam issues for several years because he monitors message boards and social media about CPAP machines.

61. The following are just a sampling of the online complaints.

62. In 2018, the user "trickyneedsleep" reported on apneaboard.com that, using the DreamStation Auto, the filters turned black within three days of use.

63. In 2019, the user "WSHenry" reported on apneaboard.com in a thread entitled "DreamStation Filter Contamination" that "both the pollen and ultra-fine filters in my machine were clogged with black (Carbon?) particles. I also noted that water chamber was completely dry. There were odd odors noted, and the water chamber was undamaged." He explained that he had recently cleaned the filters and that "[t]here was only a small amount of dust on the furniture, and the machine and tubing is clean. I do not burn candles nearby, and the furnace is off. I do have the window slightly opened, as is the case nearly year-round." He asked: "Is it possible the contamination is from the blower?"

64. In 2019, the user "Skogcat1" reported on apneaboard.com in a thread entitled "Black sticky dust in CPAP machine" that, when using the REMStar Auto, there were "sticky black dust particles" in the humidifier chamber.

65. In September 2020, Carol Nickerson posted on Facebook that she found a black mold-like substance in the water reservoir of her Philips DreamStation.

66. In June 2021, shortly after the recall was announced, on a Reddit thread entitled "Dreamstation Foam, user "BOSSHOG999" posted: "I was wondering what the hell those black particles were in my tube."

67. In addition to consumer complaints, Philip should have known about the foam problems from its prerelease testing. Medical devices go through considerable testing and design prior to release to the public.

68. As noted above, Philips's own marketing dating back to at least 2017, indicates it considered and studied the foam and noise reducing abilities extensively when designing the product.[5]

69. Furthermore, Philips already claims to know that the second-generation DreamStation 2, which it launched just before the recall, is free from the foam degradation defect. This strongly suggests that Philips was aware of and looked at the issue when developing the DreamStation 2.

70. Despite knowing about the foam deterioration defect and related health hazards for years, Philips did nothing to warn consumers, healthcare providers, or the public until very recently.

[5] *See* https://www.documents.philips.com/assets/20170523/62e4f43a1349489ba3cca77c0169c6ef.pdf (last visited July 3, 2021).

71. Furthermore, athough it has issued a "recall" of the affected products, Philips is not actually repairing or replacing them. Philips has indicated it may take over a year before it can start repairing or replacing consumers' devices. Instead, Philips is using this as an opportunity to encourage consumers to buy its second-generation products (at full price).

72. Unfortunately for patients who need to use these devices every day to stave off serious health problems, waiting over a year for Philips to offer some sort of repair is not a realistic option.

V. EQUITABLE TOLLING OF STATUTES OF LIMITATIONS

73. The running of any statute of limitations has been equitably tolled by reason of Defendants' fraudulent concealment and/or omissions of critical safety information. Through its affirmative misrepresentations and omissions, Philips actively concealed from Plaintiff and Class Members the true risks associated with the Recalled Products.

74. As a result of Defendants' actions, Plaintiff was unaware, and could not have reasonably known or learned through reasonable diligence, that she had been exposed to the risks and harms set forth herein and that those risks and harms were the direct and proximate result of Defendants' acts and omissions

VI. CLASS ALLEGATIONS

75. This action is brought, and may properly proceed, as a class action, pursuant to Rule 23(a) and 23(b)(2) and (b)(3) of the Federal Rules of Civil Procedure. Plaintiff seeks certification of a Class defined as follows ("Nationwide Class"):

> **Nationwide Class:** All persons in the United States who have purchased a Recalled Product other than for resale.

In addition, or in the alternative, Plaintiff seeks certification of the following State Class:

Virginia Class: All persons in Virginia who have purchased a Recalled Product other than for resale.

76. Excluded from the Class is Philips, its affiliates, employees, officers and directors, and the Judge(s) assigned to this case. Plaintiffs reserve the right to modify, change, or expand the class definitions if discovery and/or further investigation reveal that they should be expanded or otherwise modified.

77. The rights of each member of the Class were violated in a similar fashion based upon Defendants' uniform actions and meet the requirements for a class action under Rule 23:

a. **Numerosity**: Members of the Class are so numerous that their individual joinder is impracticable. Plaintiff is informed and believes that the proposed Class contains at least millions of individuals. The Class is therefore sufficiently numerous to make joinder impracticable, if not impossible. The precise number of Class members is unknown to Plaintiff at this time, but the Class members are readily ascertainable and can be identified by Defendants' records.

b. **Existence and Predominance of Commons Questions of Fact and Law**: Common questions of law and fact exist as to all members of the Class. These questions predominate over any questions affecting only individual Class members. These common legal and factual questions include, without limitation:

i. Whether the Recalled Products fail under the implied warranty of usability;

ii. Whether Defendants were unjustly enriched by the sale of Recalled Products;

iii. Whether Defendants were negligent in selling the Recalled Products;

iv. Whether Defendants failed to warn consumers regarding the risks of the Recalled Products

v. Whether Defendants' practices constitute unfair or deceptive acts or practices under state consumer protection statutes;

vi. The appropriate nature of class-wide equitable relief; and

vii. The appropriate measurement of restitution and/or measure of damages to Plaintiff and members of the Class.

These and other questions of law or fact which are common to the members of the Class predominate over any questions affecting only individual members of the Class.

c. **Typicality**: Plaintiff's claims are typical of the claims of all members of the Class who purchased the Recalled Products for personal use.

d. **Adequacy**: Plaintiff is an adequate representative of the Class because her interests do not conflict with the interests of the Class that she seeks to represent; she has retained counsel competent and highly experienced in complex class action litigation and she intends to prosecute this action vigorously. The interests of the Class will be fairly and adequately protected by Plaintiff and her counsel.

e. **Superiority**: A class action is superior to other available means of fair and efficient adjudication of the claims of Plaintiff and the Class. The injury suffered by each Class member is relatively small in comparison to the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Defendants' conduct. It would be virtually impossible for members of the Class to individually and effectively redress the wrongs done to them. Even if the members of the Class could afford such individual litigation, the court system could not. Individualized litigation presents a potential for inconsistent or contradictory judgments. Individualized litigation also increases the delay and expense to all parties, and to the court system, presented by the complex legal and factual issues of the case. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, an economy of scale, and comprehensive supervision by a single court.

VII. CAUSES OF ACTION

COUNT I
BREACH OF THE IMPLIED WARRANTY OF USABILTIY

78. Plaintiff and the Class incorporate by reference all preceding paragraphs.

79. By operation of law, Defendants, as manufacturers of the Recalled Products and as the providers of a limited warranty for the Recalled Products, impliedly warranted to Plaintiff and the Class that the Recalled Products were usable for their ordinary and intended use.

80. Defendants breached the implied warranty of usability in connection with the sale and distribution of the Recalled Products. At the point of sale, the Recalled Products while appearing normal—contained defects as set forth herein rendering them unusable.

81. Defendants, their agents and their employees knew or should have known that the Recalled Products suffer from a defect that causes negative health effects and/or places persons at risk for negative health effects to such an extent that the products are unusable.

82. Defendants' recall announcement instructs Class Members to not use Recalled Products because of the health risks. This renders the products unusable and thus worthless.

83. Defendants have refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Products. Plaintiff and the Class reasonably expected, at the time of purchase, that the Recalled Products were usable for their ordinary and intended use.

84. Had Plaintiff and Class Members known they would not be able to use their Recalled Products, they would not have purchased them or would have paid significantly less for them.

85. As a direct and proximate result of Defendants' breach of the implied warranty of usability, Plaintiff and the Class have sustained damages in an amount to be determined at trial.

COUNT II
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

86. Plaintiff and the Class incorporate by reference all preceding paragraphs.

87. By operation of law, Defendants, as manufacturers of the Recalled Products and as the providers of a limited warranty for the Recalled Products, impliedly warranted to Plaintiff and the Class that the Recalled Products were of merchantable quality and safe for their ordinary and intended use.

88. Defendants breached the implied warranty of merchantability in connection with the sale and distribution of the Recalled Products. At the point of sale, the Recalled Products while appearing normal—contained defects as set forth herein rendering them unsuitable and unsafe for personal use.

89. Had Plaintiff and the Class known the Recalled Products were unsafe for use, they would not have purchased them.

90. Defendants have refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Products. Plaintiff and the Class reasonably expected, at the time of purchase, that the Recalled Products were safe for their ordinary and intended use.

91. As a direct and proximate result of Defendants' breach of the implied warranty of merchantability, Plaintiff and the Class have sustained damages in an amount to be determined at trial.

COUNT III
BREACH OF EXPRESS WARRANTY

92. Plaintiff and the Class incorporate by reference all preceding paragraphs.

93. Defendants warranted the Recalled Products "shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale."

94. Defendants breached this express warranty in connection with the sale and distribution of Recalled Products. At the point of sale, the Recalled Products while appearing normal—contained immediate defects as set forth herein, rendering them unsuitable and unsafe for personal use.

95. Had Plaintiff and the Class known the Recalled Products were unsafe for use, they would not have purchased them.

96. Defendants have breached their warranty and refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Products. Plaintiff and the Class reasonably expected, at the time of purchase, that the Recalled Products were safe for their ordinary and intended use.

97. As a direct and proximate result of Defendants' breach of their express warranty, Plaintiff and the Class have sustained damages in an amount to be determined at trial.

COUNT IV
STRICT LIABILITY-FAILURE TO WARN

98. Plaintiff and the Class incorporate by reference all preceding paragraphs.

99. Defendants had a duty to warn Plaintiff and the Class members regarding the defect and true risks associated with the Recalled Products.

100. Defendants failed to provide adequate warnings regarding the risks of the PE-PUR foam.

101. Defendants had information regarding the true risks but failed to warn Plaintiff, Class members, and their physicians to strengthen their warnings.

102. Despite Defendants' obligation to unilaterally strengthen the warnings, Philips instead chose to actively conceal this knowledge.

103. Plaintiff and Class Members would not have purchased, chosen, and/or paid for all or part of the Recalled Products had they known the defect and risks of purchasing the product.

104. This defect proximately caused Plaintiff's and Class members' injuries which include economic injuries, as well as headache, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects.

105. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT V
DESIGN DEFECT STRICT LIABILITY

106. Plaintiff and the Class incorporate by reference all preceding paragraphs.

107. The design of the Recalled Products, including but not limited to design and use of the foam and the placement of the foam within the Recalled Product, was defective and unreasonably dangerous, causing degradation and inhalation of the foam, which may cause headaches, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects.

108. The design of the Recalled Products and the foam rendered the Recalled Products not reasonably fit, suitable, or safe for their intended purpose.

109. The dangers of the Recalled Products outweighed the benefits and rendered the products unreasonably dangerous. Indeed, there are other CPAP and other machines that do not use a similarly toxic foam that is subject to degradation, inhalation, and ingestions, such as Defendants' next-generation DreamStation machines.

110. Safer, alternative machines from other manufactures were available that did not suffer from the defects as set forth herein and did not have an unreasonable risk of harm as with the Recalled Products and their unsafe foam.

111. The risk benefit profile of the Recalled Products was unreasonable, and the products

should have had stronger and clearer warnings or should not have been sold in the market.

112. The Recalled Products did not perform as an ordinary consumer would expect.

113. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT VI
NEGLIGENT FAILURE TO WARN

114. Plaintiff and the Class incorporate by reference all preceding paragraphs.

115. Defendants owed Plaintiff and Class Members a duty of care and to warn of any risks associated with the Recalled Products. Defendants knew or should have known of the true risks but failed to warn Plaintiff, Class members, and their doctors.

116. Defendants' negligent breach of duty caused Plaintiff and Class members economic damages and injuries in the form of headache, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects

117. Plaintiff and Class members would not have purchased, chosen, and/or paid for all or part of the Recalled Products had they known that the risks associated with purchasing the product.

118. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT VII
NEGLIGENT DESIGN DEFECT

119. Plaintiff and the Class incorporate by reference all preceding paragraphs.

120. Defendants negligently designed the Recalled Products. Philips owed Plaintiff a duty to design the Recalled Products in a reasonable manner. The design of the Recalled Products, including but not limited to design of the foam and the placement of the foam within the Recalled Product, was defective and unreasonably dangerous, causing degradation and inhalation of the foam, and causing headaches, irritation, inflammation, respiratory issues, and exposure to materials

with toxic and carcinogenic effects.

121. The design of the Recalled Products and the foam rendered the Recalled Products not reasonably fit, suitable, or safe for their intended purpose.

122. The dangers of the Recalled Products outweighed the benefits and rendered the products unreasonably dangerous. Indeed, there are other CPAP and other machines that do not use a similarly toxic foam that is subject to degradation, inhalation, and ingestions, such as Defendants' next-generation DreamStation machines.

123. Safer, alternative machines from other manufactures were available which did not have an unreasonable risk of harm as with the Recalled Products and their unsafe foam.

124. The risk benefit profile of the Recalled Products was unreasonable, and the products should have had stronger and clearer warnings or should not have been sold in the market.

125. The Recalled Products did not perform as an ordinary consumer would expect.

126. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT VIII
NEGLIGENT RECALL

127. Plaintiff and the Class incorporate by reference all preceding paragraphs.

128. In issuing a voluntary recall, Philips assumed duties to Plaintiff and the Class to exercise reasonable care in issuing and implementing the recall.

129. Philips breached its duties by failing to adequately warn Plaintiff and the Class of the dangers associated with the use of the Recalled Products by refusing to promptly repair or replace the Recalled Products.

130. As a direct result of Defendants' breach of duty, Plaintiff and the Class have suffered harm in an amount to be determined at trial.

COUNT IX

VIOLATIONS OF THE VIRGINIA CONSUMER PROTECTION ACT VA. CODE ANN. §§ 59.1-196, *et seq.*

On Behalf of the Virginia Class

131. Plaintiff and the Class incorporate by reference all preceding paragraphs.

132. Plaintiff brings this Count on behalf of the Virginia Class.

133. The Virginia Consumer Protection prohibits "(5) misrepresenting that goods or services have certain quantities, characteristics, ingredients, uses, or benefits; (6) misrepresenting that goods or services are of a particular standard, quality, grade, style, or model; … (8) advertising goods or services with intent not to sell them as advertised …; [and] (14) using any other deception, fraud, false pretense, false promise, or misrepresentation in connection with a consumer transaction[.]" Va. Code Ann. § 59.1-200(A).

134. Philips is a "person" as defined by Va. Code Ann. § 59.1-198. The transactions between Plaintiff and the other Class members on one hand and Philips on the other, leading to the purchase of the Recalled Products by Plaintiff and the other Class members, are "consumer transactions" as defined by Va. Code Ann. § 59.1-198, because the Recalled Products were purchased primarily for personal, family or household purposes.

135. In the course of Philips's business, it willfully failed to disclose and actively concealed the defect and health risks as described above. Accordingly, Philips engaged in acts and practices violating Va. Code Ann. § 59.1-200(A), including representing that Recalled Products, including the DreamStation CPAP machine purchased by Plaintiff, have characteristics, uses, benefits, and qualities which they do not have; representing that Recalled Products are safe when they are not, representing that Recalled Products are of a particular standard and quality when they are not; advertising Recalled Products with the intent not to sell them as advertised; and otherwise engaging in conduct likely to deceive.

136. Philips's actions as set forth above occurred in the conduct of trade or commerce.

137. Philips's conduct proximately caused injuries to Plaintiff and the other Class members.

138. Plaintiff and the other Class members were injured as a result of Philips's conduct in that Plaintiff and the other Class members overpaid for their Recalled Products and did not receive the benefit of their bargain, and their Recalled Products are now worthless, and they must now purchase new ones. These injuries are the direct and natural consequence of Philips's misrepresentations and omissions.

139. Philips actively and willfully concealed and/or suppressed the material facts regarding the defective and unsafe nature of the Recalled Products, in whole or in part, with the intent to deceive and mislead Plaintiff and the other Class members and to induce Plaintiff and the other Class members to purchase Recalled Products at a higher price, which did not match the true value. Plaintiff and the other Class members therefore seek treble damages.

COUNT X
UNJUST ENRICHMENT
In the Alternative

140. Plaintiff and the Class incorporate by reference all preceding paragraphs.

141. Plaintiff and the Class members conferred a tangible and material economic benefit upon Defendants by purchasing the Recalled Products. Plaintiff and Class members would not have purchased, chosen and/or paid for all or part of Recalled Products had they known that they the true risks of using the Recalled Products while Defendants cannot provide a timely repair or replacement for the Recalled Products. Under these circumstances, it would be unjust and inequitable for Defendants to retain the economic benefits they received at the expense of Plaintiff and the Class.

142. Failing to require Defendants to provide remuneration under these circumstances would result in Defendants being unjustly enriched at the expense of Plaintiff and the Class members who endure being exposed to the risk of developing serious medical conditions and can no longer use their machines safely.

143. Defendants' retention of the benefit conferred upon them by Plaintiff and the Class would be unjust and inequitable.

144. Plaintiff and the Class suffered damages in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests, individually and on behalf of the Class, that this Court:

A. determine that the claims alleged herein may be maintained as a class action under Rule 23(a), (b)(2), and/or (b)(3) of the Federal Rules of Civil Procedure on behalf of the Nationwide Class and State Class defined above, and designate Plaintiff as the class representative and Plaintiffs' counsel as counsel for the Nationwide Class and Virginia Class;

B. award equitable and injunctive relief, including but not limited to, requiring Defendants to institute a medical monitoring program for Class members, restitution, and disgorgement of profits;

C. award all actual, general, special, incidental, punitive, and consequential damages to which Plaintiff and Class members are entitled;

D. award pre-judgment and post-judgment interest on such monetary relief;

E. award reasonable attorneys' fees and costs; and

F. grant such further and other relief that this Court deems appropriate.

JURY DEMAND

Plaintiff and the Class demand a trial by jury on all issues so triable.

Dated: July 5, 2021

Respectfully Submitted,

By: */s/ Alex M. Kashurba*
Steven A. Schwartz (PA ID No. 50579)
Benjamin F. Johns (PA ID No. 201373)

Beena M. McDonald (PA ID No. 83315, *pro hac vice* to be filed)
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